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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/773,691	02/06/2004	Vinod B. Shidham	128880.00002	7800	
26710 QUARLES & 1	7590 11/14/2007 BRADY LLP		EXAMINER		
411 E. WISCONSIN AVENUE			TOWA, RENE T		
	SUITE 2040 MILWAUKEE, WI 53202-4497		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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1		Application No.	Applicant(s)	<u> </u>		
		10/773,691	SHIDHAM ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Rene Towa	3736			
Period fo	The MAILING DATE of this communication apport Reply	pears on the cover sheet with the	correspondence address			
WHI(- Exte after - If NO - Failu Any	CHEVER IS LONGER, FROM THE MAILING D. Inside the may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Depriod for reply is specified above, the maximum statutory period our to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON	DN. timely filed m the mailing date of this communica NED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 30 A	ugust 2007.				
2a)⊠	This action is FINAL . 2b) This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	453 O.G. 213.			
Disposit	ion of Claims					
4)⊠	Claim(s) 40-44 and 47-58 is/are pending in the	e application.	•			
	4a) Of the above claim(s) is/are withdra	wn from consideration.				
5)	Claim(s) is/are allowed.			•		
	Claim(s) 40-44 and 47-58 is/are rejected.					
·	Claim(s) is/are objected to.					
8)[_]	Claim(s) are subject to restriction and/o	r election requirement.				
Applicat	ion Papers					
9)	The specification is objected to by the Examine	er.				
10)	The drawing(s) filed on is/are: a) acc	epted or b)□ objected to by the	Examiner.			
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. S	ee 37 CFR 1.85(a).			
11)[Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	- · · · · · · · · · · · · · · · · · · ·	· •	` '		
Priority (under 35 U.S.C. § 119					
12)	Acknowledgment is made of a claim for foreign All b) Some * c) None of:		a)-(d) or (f).			
	1. Certified copies of the priority document					
	2. Certified copies of the priority document	• •				
	 Copies of the certified copies of the prio application from the International Bureau 		ved in this National Stage			
* 5	See the attached detailed Office action for a list	` ','	ved .			
Attachmen		_				
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summai Paper No(s)/Mail I				
3) Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date		Patent Application (PTO-152)			

DETAILED ACTION

1. This Office action is responsive to an amendment filed August 30, 2007. Claims 40-44 and 47-58 are pending. Claims 1-39 and 45-46 are cancelled. No new claim has been added. Claims 40, 42, 44, 47-51 and 55 been amended.

Claim Objections

Claims 40-44 are objected to because of the following informalities:
 In regards to claim 40, at line 2, "devise" should apparently read --device---.
 Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At line 1, the claims recite "The device of claim 40," "The device of claim 41," "The device of claim 40," and "The device of claim 43," respectively; however, claim 40, from which claims 41-44 depend pertains to "A high specimen yield anti-reflux head for a needle biopsy device" [Emphasis added], as such, the limitations "The device" lack sufficient antecedent basis and/or it is unclear whether the claims 41-44 pertain to the "biopsy device."

Claim Rejections - 35 USC § 103

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5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 40, 43-44 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US 4,967,762) in view of Zucker (US 5,086,782).

In regards to **claims 40 and 47-49**, DeVries discloses a high specimen yield antireflux head for a needle aspiration biopsy device comprising:

a hub 40 defining a specimen collection well 62 and mounting a needle 70 having a shaft with an open pointed tip; and

a sample passageway 64 extending from the pointed tip of the needle 70 to a segment inside the hub opening in spaced relation to a floor of the collection well 62 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 defines an opening 64 in the floor of the collection well 62 through which the needle shaft extends (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the proximal end of the needle 70 in part follows the contour of the collection well 62 (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 includes an outer grip 52 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 has an open mouth 50 allowing access to the collection well 62 (see fig. 2).

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In regards to **claim 43**, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the passageway 64 is defined in part by the needle 70 and in part by an internal channel in the hub 40 (see fig. 2).

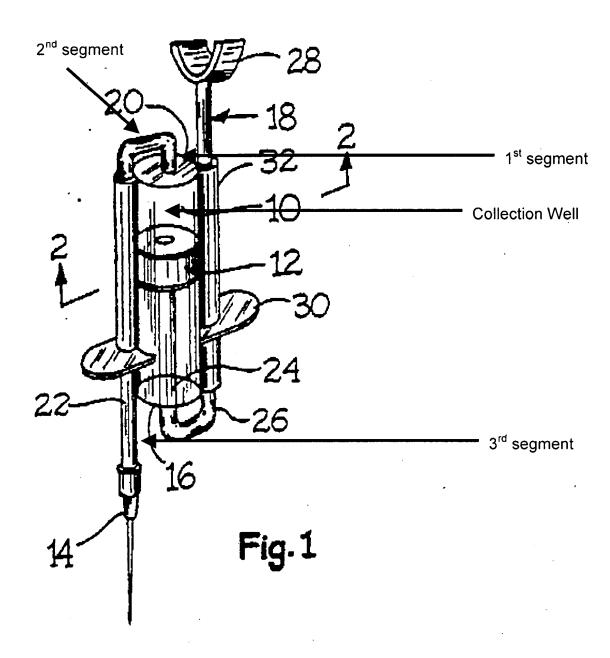
In regards to **claim 44**, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

DeVries discloses an apparatus, as described above, that fails to explicitly teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor.

However, Zucker discloses an anti-reflux head comprising a sample passageway defined by a first segment extending from an internal opening at an angle (i.e. zero degree) to the long axis, a second segment extending continuously from the first segment, a portion of which is concentric about an axis spaced from the long axis, and a third segment extending continuously from the second segment to be concentric with the long axis without passing through the collection well floor such that a specimen can pass through the needle 14 and be deposited in the collection well from above the floor; wherein sample passageway is defined by a combination of the needle and the internal passage; wherein the needle has a straight proximal end (see fig. 1).

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In regards to **claims 40** and **47-49**, Since Zucker discloses a collection device arranged such that reduced pressure within the collection well causes enables

withdrawal of a sample with a one hand grasping operation (see col. 1, lines 33-42), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a collection head similar to that of DeVries to include a sample passageway and collection well arranged similar to that of Zucker in order to enable withdrawal of a sample with a one hand grasping operation.

In regards to **claims 43-44**, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker, above, with a passageway wherein the passageway is defined in part by the needle and in part by a channel similar to that of Zucker since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

7. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US 4,967,762) in view of Zucker ('782) further in view of Guerra (US 3,753,432).

DeVries as modified by Zucker discloses a system, as described above, that fails to explicitly teach a passageway wherein the needle defines the entire passageway.

However, Guerra discloses an apparatus comprising a specimen passageway wherein a specimen can pass through the needle 18B and be deposited in the collection well 19 from above the floor; wherein the internal passage does not pass the collection well floor; Guerra further discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at

an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular; wherein the needle defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker, above, with a passageway wherein the needle defines the entire passageway similar to that of Guerra since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable---See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

8. Claims 50 & 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) further in view of Ellingson et al. (US 6,217,556).

In regards to **claim 50**, DeVries discloses a high specimen yielding needle aspiration biopsy device, comprising:

a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;

a hub 40 and defining a specimen collection well 62; and

a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

DeVries discloses a system, as described above, that fails to explicitly teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor or a valve for controlling an opening in the syringe barrel.

However, Zucker discloses an anti-reflux head comprising a sample passageway defined by a first segment extending from an internal opening at an angle (i.e. zero degree) to the long axis, a second segment extending continuously from the first segment, a portion of which is concentric about an axis spaced from the long axis, and a third segment extending continuously from the second segment to be concentric with the long axis without passing through the collection well floor such that a specimen can pass through the needle 14 and be deposited in the collection well from above the floor; wherein sample passageway is defined by a combination of the needle and the internal passage; wherein the needle has a straight proximal end (see fig. 1).

Ellingson et al. disclose a coupler with the valve 23 for controlling an opening in a syringe barrel 63 (see fig. 1) and a coupler 35 (see fig. 1-3B).

In regards to **claim 50**, Since Zucker discloses a collection device arranged such that reduced pressure within the collection well causes enables withdrawal of a sample with a one hand grasping operation (see col. 1, lines 33-42), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a collection head similar to that of DeVries to include a sample passageway and collection well arranged similar to that of Zucker in order to enable withdrawal of a sample with a one hand grasping operation.

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker, above, with a valve similar to that of Ellingson et al. in order to control the flow of fluid (see Ellingson et al., column 3/lines 17-22).

In regards to **claim 52**, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker, above, with a passageway wherein the passageway is defined in part by the needle and in part by a channel similar to that of Zucker since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

In regards to **claim 53**, it would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Ellingson et al. with a coupler containing a valve similar to that of Ellingson et al. in order to selectively connect establish a fluid communication between the hub and the syringe.

9. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) and Ellingson et al. ('556) further in view of Guerra ('432).

DeVries as modified by Zucker and Ellingson et al. discloses a system, as described above, that fails to explicitly teach a passageway wherein the needle defines the entire passageway.

However, Guerra discloses an apparatus comprising a specimen passageway wherein a specimen can pass through the needle 18B and be deposited in the collection well 19 from above the floor; wherein the internal passage does not pass the collection well floor; Guerra further discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular; wherein the needle defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Ellingson et al., above, with a passageway wherein the needle defines the entire passageway similar to that of Guerra since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

10. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) further in view of Ellingson et al. ('556) even further in view of Banys et al. ('376).

DeVries as modified by Zucker and Ellingson et al. disclose a system, as described above, that fails to explicitly teach a piston lock.

However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6).

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It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Ellingson et al., above, with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

11. Claims 50, 52 & 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) further in view of Markham (US 4,549,554).

In regards to **claim 50**, DeVries disclose a high specimen yielding needle aspiration biopsy device, comprising:

a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;

a hub 40 and defining a specimen collection well 62; and

a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to **claim 55**, DeVries discloses a method as follows:

inserting the needle 70 into a specimen sample site;

communicating a vacuum to the needle 70;

probing the specimen sample site with the needle 70 to collect specimens in the collection well of the hub 40;

releasing the vacuum in the needle 70;

withdrawing the needle 70 from the specimen sample site;

separating the hub from the device; and

transferring specimens collected in the hub to an examination site (see DeVries, column 1/lines 55-72; column 2/lines 3-12; column 3/lines 1-3 & 8-14).

DeVries discloses a system, as described above, that fails to explicitly teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor, a valve for controlling an opening in the syringe barrel or the steps of creating a vacuum by closing a valve and pulling a piston.

However, Zucker discloses an anti-reflux head comprising a sample passageway defined by a first segment extending from an internal opening at an angle (i.e. zero degree) to the long axis, a second segment extending continuously from the first segment, a portion of which is concentric about an axis spaced from the long axis, and a third segment extending continuously from the second segment to be concentric with the long axis without passing through the collection well floor such that a specimen can pass through the needle 14 and be deposited in the collection well from above the floor; wherein sample passageway is defined by a combination of the needle and the internal passage; wherein the needle has a straight proximal end (see fig. 1).

However, in regards to **claim 50**, Markham discloses a valve 28 for controlling an opening in a syringe barrel 63 and a coupler 34 (see figs. 1-2).

In regards to **claim 55**, Markham discloses a method of needle aspiration biopsy, comprising the steps of:

creating a vacuum in the syringe 10;

inserting the needle 36 into a specimen sample site;

communicating the vacuum to the needle 36 (see figs. 1-2);

probing the specimen sample site with the needle 36 to collect specimens in the collection well of the hub;

releasing the vacuum in the needle 36;

withdrawing the needle 36 from the specimen sample site;

separating the hub from the device; and

transferring specimens collected in the hub to an examination site (see figs. 1-2) column 4/lines 23-28, 37-43 & 59-64).

In regards to **claim 56**, Markham discloses a method of needle aspiration biopsy wherein the step of creating a vacuum in the syringe 10 includes closing the valve 28 and pulling the syringe piston 22 away from the syringe barrel 12 (see column 4/lines 23-28).

In regards to **claim 57**, Markham discloses a method of needle aspiration biopsy wherein the vacuum is communicated to the needle 36 by opening the valve 28 (see column 4/lines 37-43).

In regards to **claim 58**, Markham discloses a method of needle aspiration biopsy wherein the step of releasing the vacuum in the needle 36 includes reclosing the valve 28 (see column 4/lines 59-64).

In regards to **claim 50**, Since Zucker discloses a collection device arranged such that reduced pressure within the collection well causes enables withdrawal of a sample

with a one hand grasping operation (see col. 1, lines 33-42), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a collection head similar to that of DeVries to include a sample passageway and collection well arranged similar to that of Zucker in order to enable withdrawal of a sample with a one hand grasping operation.

Moreover, since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra with a stopcock valve similar to that of Markham in order to control the flow of fluid to the syringe barrel as is well known in the art (see Markham, figs. 1-2).

In regards to **claim 52**, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Markham, above, with a passageway wherein the passageway is defined in part by the needle and in part by a channel similar to that of Zucker since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

In regards to **claim 55**, since both DeVries and Markham teach needle biopsy devices for collecting a biopsy sample, it would have been obvious to one ordinary skill

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in the art at the time Applicant's invention was made to provide a method similar to that of DeVries with method steps similar to that of Markham in order to controllably collect the biopsy sample.

In regards to **claims 56-58**, since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra with a stopcock valve similar to that of Markham in order to control the flow of fluid to the syringe barrel as is well known in the art (see Markham, figs. 1-2).

12. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) and Markham ('554) further in view of Guerra ('432).

DeVries as modified by Zucker and Markham discloses a system, as described above, that fails to explicitly teach a passageway wherein the needle defines the entire passageway.

However, Guerra discloses an apparatus comprising a specimen passageway wherein a specimen can pass through the needle 18B and be deposited in the collection well 19 from above the floor; wherein the internal passage does not pass the collection well floor; Guerra further discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes

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are essentially perpendicular; wherein the needle defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Markham above, with a passageway wherein the needle defines the entire passageway similar to that of Guerra since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable---See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

13. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) and Markham ('554) further in view of Ellingson et al. ('556).

DeVries as modified by Zucker and Markham disclose a high specimen yield biopsy device, as described above, that fails to explicitly teach a coupler.

However, Ellingson et al. disclose a system comprising a coupler 23 (see figs. 1-3B).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Zucker and Markham with a coupler similar to that of Ellingson et al. in order to selectively connect establish a fluid communication between the hub and the syringe.

14. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Zucker ('782) and Markham ('554) further in view of Banys et al. ('376).

DeVries as modified by Guerra and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Guerra and Markham do not teach a piston lock.

However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Zucker and Markham with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

Response to Arguments

15. Applicant's arguments filed August 30, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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